

Remarks

Claims 15-32 were originally pending in the subject application. Claims 26-32 have been withdrawn from consideration pursuant to an Election submitted by the applicants dated September 28, 2007. The Office Action notes that claim 19 is currently withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, because the Examiner believes that there is no allowable generic or linking claim. The applicants respectfully dissent from this view and request reconsideration of the withdrawal of claim 19 in view of the arguments set forth below regarding the generic claims.

With the current withdrawal of claim 19, claims 15-18 and 20-25 are pending in the subject application and are now presented to the Examiner for further review. Favorable consideration of these claims, in view of the remarks set forth herein, is earnestly solicited.

Initially, the Office Action states that correction is needed to the Declaration and Power of Attorney form because the citizenship for Hans Dieter is listed as “German” and is not a proper country. Attached herewith is an Application Data Sheet that corrects the country of citizenship from “German” to “Germany.”

The drawings have also been objected to because verbiage in Figures 1, 3, and 4 is in a foreign language. Attached herewith are amended Figures 1, 3, and 4.

Claims 15-18 and 20-25 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fong (*The Journal of Infectious Diseases*, 2000, Vol. 181, Suppl. 3, pp. S514-S518) in view of Vlasselaer *et al.* (US 2001/0043906). The applicants respectfully traverse this ground of rejection because, once the current invention is fully understood and appreciated, it can be seen that the cited references, taken either alone or in combination, do not disclose or suggest the claimed subject matter.

The present invention provides methods for preventive anti-infective therapy after acute stroke. Therapy starts at a point in time when a stroke has occurred but a bacterial infection has not yet occurred in the patient. Both Vlasselaer *et al.* and Fong refer to the treatment of an infection, i.e. administration of an active compound after the onset of a bacterial infection. Vlasselaer *et al.* and Fong teach treating a patient with gamma-IFN and moxifloxacin, respectively, after the outbreak of an infection for treatment purposes (see, for example, Fong, p. S515, abstract line 6, and paragraph

[0082] of Vlasselaer *et al.*, "for as long as the condition exists and is in need of control."). There is no suggestion in these references of applying treatment in the absence of an established infection.

Advantageously, and in contrast to the cited references, the current invention provides methods for preventing debilitating infections that so often occur after an acute stroke. These infections can be, for example, pneumonias, infections of the urinary tract, and sepsis. It was found, that a cellular-functional immunodepression, which is mainly mediated by the sympathetic nervous system (SNS), occurs after a stroke, wherein this immunodepression is so severe, that it can lead to the spontaneous development of severe, prognosis-determining infections.

Thus, in the course of 2 to 4 days after a stroke, a severe infection often spontaneously arises. This infection can be, for example, a bacterial sepsis and/or pneumonia with a high rate of lethal outcomes. These complications cause a delayed acute-stationary progress and thus prevent the necessary and effective early-stage rehabilitation. They are to a large extent responsible for the relatively high lethality after acute stroke (Henon *et al.* 1995, Katzan *et al.* 2003; cited in the applicants' specification). These complications lead to fever, another independent risk factor for a negative prognosis after acute stroke (Castillo *et al.* 1998). The treatment of these complications thus reduces lethality and morbidity after acute stroke.

Through the early administration of a preventive anti-infective therapy (in the case of moxifloxacin preferably within the first 24 hours) in accordance with the subject invention, lethality and the neurological deficit are drastically reduced. In a further aspect of the invention, it is possible to prevent the development of infections by means of immunomodulating agents such as beta-blockers or by the administration of IFN- γ .

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield applicant's invention does not make the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." *In re Dow Chemical Co.* 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). As is clearly shown by the foregoing remarks, one finds neither the suggestion nor the expectation of success in the cited references, either separately or combined. An assertion of obviousness without

the required suggestion or expectation of success in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Spinnoble*, 56CCPA 823, 160 USPQ 237, 243 (1969).

The preventive therapy of the subject invention constitutes a novel therapeutic approach in the treatment of stroke patients, this approach can be used to reduce lethality and morbidity through the prevention of the commonly occurring complications of infections. This is not disclosed or suggested by the Vlasselaer *et al.* and Fong references. Therefore, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103 based on Fong in view of Vlasselaer *et al.*

In view of the foregoing remarks, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

A handwritten signature in black ink, reading "David R. Saliwanchik". The signature is fluid and cursive, with the first name "David" and last name "Saliwanchik" clearly distinguishable.

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